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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,617

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Lynette A. Zaidel

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,617

Applicant(s)

ZAIDEL ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Priority

Applicant is requested to amend the first line of the specification to read:

"This application is a continuation of United States application no. 10/065,244, filed 09/27/2002."

Claim Informalities

The following changes are recommended to correct minor errors in grammar or form:

- i) Claim 1, sixth line, the word "when" should be inserted after "whereby".
- ii) Claim 1, seventh line, "when" should be changed to --- are ---
- iii) Claim 4, second line, "on" should be changed to --- of ---
- iv) Claims 8 and 21, first line of each claim, in each instance the terms "dentrifice" and "component" should be transposed, i.e., so that the claim reads --- second dentrifice component ---
- v) Claims 13 and 26, first line of each claim, in each instance "peroxide" should be changed to --- dentrifice ---

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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i) The following terms in claims 1 and 14 are relative terms which render those claims indefinite:

"enhanced " (first and eighth lines of each claim);

"minimal" (second line of claim 1, first line of claim 14);

"rapidly" (penultimate line of claim 1, last line of claim 14); and

"substantial" (last line of each claim).

These terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The indefiniteness of all four terms appears to arise from a common source, namely the failure of the claims to set forth the basis for comparison, e.g. "enhanced" compared to what? Indeed, the terms merely appear to recite characteristics already inherent in the claimed components/compositions, i.e. a whitening agent by definition provides "enhanced" whitening over a dentrifice lacking a whitening agent and a densensitizing agent by definition minimizes irritation and tooth sensitivity. Accordingly, any function of these terms as modifiers of such claimed properties is unclear; rather, they appear superfluous.

ii) Claim 12, the phrase "the peroxide reactive dye" lacks antecedent basis. (Claim 12 should depend from claim 11, not claim 10).

iii) Claims 15-26 are method claims, but all ultimately depend from claim 13, which is drawn to a composition. Accordingly, the term "method" as used at the first line of each of claims 15-26 lacks antecedent basis. (These claims should ultimately depend from claim 14, not claim 13).

iv) Claim 18, the phrase "the phosphate salt" lacks antecedent basis. (Claim 18 should depend from claim 17, not claim 16).

v) Claim 20, the phrase "the potassium salt" lacks antecedent basis. (Claim 20 should depend from claim 19, not claim 18).

vi) Claim 25, the phrase "the reactive dye" lacks antecedent basis. (Claim 25 should depend from claim 24, not claim 22).

Applicant should note that, in the interest of advancing prosecution and for the sake of clarity, the obviousness rejections which follow infra have been constructed based on the presumption that Applicant will make the obvious changes necessary to correct the lack of antecedent basis as outlined in subsections "ii)" through "vi)" above.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-7, 9, 10, 14-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al (USP 5,766,574).

The primary reference discloses dual component dentrifice compositions comprising a separately maintained first component containing a peroxide and an abrasive system compatible with the peroxide, and a second component containing an abrasive incompatible with the peroxide, which when mixed and combined are applied to teeth to enhance whitening. Preferred peroxides are hydrogen peroxide and urea peroxide (col. 3, lines 6-13), and preferred peroxide-compatible abrasives are calcium phosphate salts such as calcium pyrophosphate (col. 4, lines 11-22). See also working example 1 at col. 7, where urea peroxide is used in an amount of 6.60 percent by weight.

The prior art is not anticipatory of the instant claims because it does not exemplify, in the form of a preferred embodiment or working example, a dentrifice containing a desensitizing agent. It does, however, clearly suggest using one (e.g. potassium nitrate) as an optional ingredient for addition to the second (non-peroxide) component. See col. 6, lines 38-43. It would have been obvious to have incorporated a desensitizing agent in the prior art dentrifices, then, simply by following this clear suggestion to do so and motivated by the desire to obtain the art-recognized benefits associated therewith (i.e., decreased tooth sensitivity and gum irritation). The selection of an appropriate amount of desensitizer, i.e. 3 to 10 percent by weight as required by instant claim 10, is well within the skill of the ordinary artisan and would have been obvious, motivated by the desire to provide optimal performance. This position is fully consistent with well established precedent. See for example In re Aller, 105 USPQ 233, 235 (CCPA 1955). (Holding that the determination of workable conditions is generally obvious because such determinations are within the routine abilities of one skilled in the art.) See also In re Boesch, 205 USPQ 215 (CCPA 1980). (Holding the same with regard to the determination of optimal conditions).

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2) Claims 8, 11, 13, 21, 24 and 26 are rejected under 35 U.S.C. 103 as being unpatentable over Christina-Beck et al (USP 5,766,574) in view of Sharma (USP 6,036,493).

The primary reference is discussed in subsection "1)" supra. It differs from the instant claims insofar as it does not specifically disclose:

- i) adjusting the pH of the second (non-peroxide) component with an alkali metal hydroxide or carbonate salt (claims 8 and 21);
- ii) adjusting the pH of the first component to 4 to 7 and the pH of the second component to 8 to 13 (claims 13 and 26); and
- iii) adding a peroxide-reactive dye to the second component as a reaction indicator (claims 11 and 24).

The use of peroxide reactive dyes as indicators in dental bleaching systems is well-known. The secondary reference recognizes this general state of the art (col. 2, lines 3-12) and discloses an indicator system specifically for use in two component dental systems. Such systems contain a peroxide reactive redox color indicator in the second (non-peroxide) component such as guinea green. See col. 5, lines 15-30. Moreover, the pH of the second component is raised by adding a base, e.g. an alkali metal hydroxide or carbonate salt in order to provide improved stability and control over reaction rate, while simultaneously minimizing tooth etching and gum irritation. See the passage spanning col. 4, line 61 to col. 5, line 14. When the overall pH of the dentrifice is 7 or 8 (see col. 5, lines 6 and 7), this means that a basic pH (8 or greater) in the second component would require a corresponding acid pH (6 or less) in the first component, as required by instant claims 13 and 26. The secondary reference thus differs substantively from the instant claims insofar as it is silent regarding the use of a peroxide-incompatible abrasive in the second component.

It would have been obvious to have incorporated a redox color indicator in the second (non-peroxide) component and to have adjusted the pH of same to an alkaline pH (and thus the pH of the first component to an acidic one) in the primary reference bleaching systems, motivated by the desire to improve accuracy of administration and increase stability while minimizing tooth and gum irritation as taught by the secondary reference.

3) Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al (USP 5,766,574) in view of Sharma (USP 6,063,493), the combination being considered in view of the Chemical Abstract Registry Number Data Printouts for the dyes "Guinea Green" and "FD & C Green No. 3".

The primary and secondary references and the rationale for combining their teachings is provided in subsection "2)" supra. The combined teachings of these references differ from the instant claims insofar as use of the particular dye FD&C Green No. 3 as an indicator is not specifically disclosed. The secondary reference does clearly suggest using redox color indicators which are "capable of being oxidized by hydrogen peroxide such as guinea green or phenolphthalein and the like" at col. 5, lines 15-17.

FD&C Green No. 3 (well known as green food coloring) is structurally very similar guinea green, as a review of the data printouts for each compound's respective Chemical Abstract Registry Numbers demonstrates. (See attached printouts). FD&C Green No. 3 would clearly be a redox dye since it contains a core structure which is identical to that of guinea green (the only difference between the two compounds resides in the presence of an additional solubilizing substituent (an additional arylsulfonate group) in the latter).

It would have been obvious to have used FD&C Green No. 3, instead of guinea green, as the redox color indicator of the dentrifices suggested by the combined teachings of the primary and secondary references, based on the reasonable expectation of equivalent function arising from the close structural similarity of the two dyes as illustrated by their Chemical Abstract Registry Number printouts. This position is fully consistent with established precedent. See In re Gyurik, 596 F.2d 1012, 1018 (1979). (Holding that the necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure, and having the same utility, will have similar properties). Further motivation to use one dye in place of another would arise from aesthetic/marketing considerations, e.g. the desire to provide a difference in shade between products.

Provisional Statutory Double Patenting Rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-11, 13 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11, 13 and 14 of copending Application No. 10/065,244. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant will further note that claims 12 and 15-26 would be subject to this same rejection upon correction of their improper dependencies (see subsections "ii)" through "vi) of the "Indefiniteness" section supra.)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

